

## REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claim 9 has been amended to delete previous step (a). Previous step (b) is renamed step (a), and the new step (a) clarifies that the  $CD4^{+} CD25^{-}$  T cells are anergized by contact with  $CD4^{+} CD25^{-}$  T cells and the results of such anergizing are Tr1-like regulatory cells. A new step (b) is also added. These changes are supported by, for example, item (2) in middle of page 3 of the instant application and, also, original claim 4, which supports the concept that the Tr1-like regulatory cells obtained can be isolated. Support for new step (b) can also be found in instant Examples 4 and 5, where it is shown, merely for example, that separated (i.e., FACS-sorted) anergized  $CD4^{+} CD25^{-}$  T cells suppressed proliferation of syngeneic  $CD4^{+} CD25^{-}$  T cells mediated by IL-10.

New claims 35 and 36 are both supported by item (4) towards the bottom of page 3 of the instant application.

Applicants do not believe that any of the amendments above introduce new matter. An early notice to that effect is earnestly solicited.

The Examiner withdrew claims 31-34 as being drawn to an invention that was independent or distinct from the subject matter originally claimed. Applicants have now canceled these claims without prejudice to prosecuting the subject matter of these claims in a divisional application.

Claims 9, 11, 29 and 30 were rejected under 35 USC §112, first paragraph, as claiming new matter. In response to the Examiner's concern A), Applicants point out that claim 9 has been amended to correct a typographical error. Thus, in new step (a) of claim 9, the last occurrence of "CD4<sup>+</sup> CD25<sup>-</sup> T cells" has been deleted and replaced by -- CD4<sup>+</sup> CD25<sup>+</sup> T cells --. Applicants respectfully submit that this removes the Examiner's concern A). An early notice to that effect is earnestly solicited.

With respect to the Examiner's concern B), Applicants have deleted previous step (a), but merely to advance the prosecution. Applicants believe the original disclosure amply supports previous step (a). In any case, Applicants point out that claim 9 uses the open-ended terminology "comprising." Therefore, claim 9 provides protection in the event an unauthorized party should combine previous step (a) + current steps (a) and (b).

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 9, 11, 29 and 30 were rejected under 35 USC § 102(b) as being anticipated by Baecher-Allan et al. ("Baecher-Allan"), *J. Immunol.*, 167: 1245-1253 (2001). In response, Applicants point out that Baecher-Allan's focus is on the CD4<sup>+</sup> CD25<sup>+</sup> T cells and their ability to inhibit proliferation and cytokine secretion by activated CD4<sup>+</sup> CD25<sup>-</sup> responder T cells. Instant Applicants were the first to focus attention on the anergized CD4<sup>+</sup> CD25<sup>-</sup> T cells themselves and to recognize that these anergized CD4<sup>+</sup> CD25<sup>-</sup> T cells had suppressive properties themselves and, therefore, could be used to suppress the proliferation of CD4<sup>+</sup> T cells. Thus, Baecher-Allan does not teach or suggest separation

after anergizing of Tr1-like regulatory cells from anergizing CD4<sup>+</sup> CD25<sup>+</sup> T cells, as required by the instant claims.

In view of the foregoing, Applicants respectfully submit that Baecher-Allan does not anticipate the present claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

#### **CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

#### **ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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